

Principal Investigator:
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CONSENT FORM

STUDY: THE EFFECT OF ETS, DOG AND CAT ALLERGY, AND SMOG
ON ASTHMA IN THE ELDERLY

Based on the findings of your asthma questionnaire and examination of the spirometries, you are invited to participate in this research study on the effect of ETS and smog on asthma. The purpose of this study is to examine the effect of smog, dogs and cats, and ETS on asthma. The study will attempt to discover whether there is a direct relationship between the three above factors. You will receive no medical benefit from participation in this study, although information provided from this study may possibly be of benefit to you as a potentially asthmatic patient and could be of benefit to other asthmatic patients who live in an area of high smog levels.

You and up to 60 other volunteers will be asked to do lung function tests. You will breathe into a computerized spirometer which will measure your lung function. This will tell us and you whether you have a reversibility in your lung capacity. If the lung capacity gets better and worse with time or with treatment, by definition you have bronchial asthma. We would like to follow your lung function by having you do periodic breathing into a peak flow meter over the next two and a half to three years.

In addition, we will solicit help of the asthmatics in the study and some normals. We will attempt to identify whether ETS, dogs and cats, and the component of smog, ozone, are related to worsening asthma. To do this, we will ask you to spend from two to four hours in a "challenge chamber." While in this chamber, one of you, a smoker, will smoke ten or 20 cigarettes over a two or four hour period. During this time, periodically your lung function will be analyzed with a comput-

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erized lung function analyzer. In addition, one of the two occupants of the chamber will be a non-smoker. The non-smoker will serve to help define the effect of second-hand smoke on the airways function.

In addition, a second group of experiments will include smoking plus ozone in individuals exposed to both in the challenge chamber. The amount of ozone introduced into the chamber will be essentially the same as that in a first stage smog alert or 0.200 parts per million of ozone within the chamber.

This is a relatively small amount of ozone and, by itself in non-exercising individuals, should not induce asthma.

At the beginning of the study, you will perform lung function tests to determine whether or not you have asthma.

A very preliminary physical exam and history will be taken at the beginning of the study.

Your lung function, as mentioned above, will be monitored over a period of two and a half to three years. A number of individuals, 60 or more, will be asked to participate in the challenge chamber studies. These studies will involve anywhere from two to four hour sessions within the chamber. Prior to going into the chamber to be tested for smoke or ozone sensitivity, your lung function will be measured, and a measurement of lung hyperreactivity will be performed. To test for lung twitchiness, you will be asked to inhale relatively small amounts of a chemical called methacholine. This chemical causes bronchial constriction. Your lung function will be measured after varying amounts of the chemical to see if, by definition, you have asthma. If your lung function gets worse when inhaling this chemical, you will be given two puffs of Albuterol to reverse the asthma and make your lung function better.

During the chamber studies, it would be useful to get sputum and saliva and urine samples to measure the effect of cigarette smoke on fluids in your body. In addition, other chemicals within the chamber will be carefully monitored so that there is little or no danger from excess chemicals within the chamber.

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The study will last for a total of three years. You will be asked to keep a relatively simple diary to test whether your lung function and clinical symptoms are stable or whether there is some worsening in the asthma. In addition, we will measure the amounts of smog, ozone, nitrogen dioxide, and sulfur dioxide as well as particulates in an attempt to identify whether your lung function and those of others in the study are affected by different amounts of smog.

Dust and air samples will be collected from some patients' homes to measure ozone and dog and cat allergens. Some patients will be asked to get rid of dogs or cats to check the effect of pet removal on asthma.

Also, some dog and cat allergic patients will be tested for asthma by inhaling small quantities of dog or cat allergen solutions through a nebulizer. If asthma is provoked by animal extract inhalation, it will be reversed by Proventil inhalation.

Certain changes in body functioning can take place when any person is exposed to cigarette smoke. These can include but not be limited to coughing, wheezing, increased difficulty breathing, and feelings of nausea and malaise.

If during any time while you are in the challenge chamber you feel ill, we will encourage you to come out and to terminate the test immediately. While you are being tested in the chamber, you will be observed on a continuous basis, and if our investigators feel that it is of danger to you, we will ask you to immediately stop the testing.

You may choose to be treated or stop participation in the study at any time. Alternative therapies are available to you. While being tested in the chamber, it is necessary that you not take inhaled bronchodilators for 12 hours prior to the chamber testing. You may continue to take inhaled cortisone preparations and/or theophylline, which will not affect the results of our studies.

Should you desire to withdraw from the study, you may do so at any time for any reason without penalty or loss of benefits to which you are entitled. Participation is voluntary and

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refusal to participate will involve no penalty of loss of benefits to which you are otherwise entitled. All of the results of the study are available to your physician at any time, should he so desire to see them.

If, during the course and as a result of participation in the study, any physical injuries shall occur to you which is caused by any substance ingested or administered due to the protocol, you will be treated by the Asthma and Allergy Center immediately. There is little danger of severe or marked untoward reactions as a result of the challenge chamber testing.

If there is any other information that you would desire, I would be happy to provide it to you. By signing this form, you acknowledge that the scope of the testing has been described to you and that you willingly participate in this research study of the Huntington Memorial Hospital Asthma and Allergy Center.

Signatures

Participant

Witness